## DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

5903. Herbal drugs. (Inj. No. 303.)

COMPLAINT FOR INJUNCTION FILED: 10-11-56, W. Dist. Wash., against Forward Club, a corporation, Seattle, Wash., James L. Evans, president of the corporation, and Otto Soles, vice president of the corporation and also doing business as Keystone Laboratories, Portland, Oreg.

CHARGE: The complaint alleged that the defendants were causing and had caused to be introduced into interstate commerce at Seattle, Wash., and Portland, Oreg., certain herbal drugs, among which were articles designated as Keystone Blood and Kidney Remedy, Keystone Liniment, Keystone Salve, Keystone Hair Regenerator, Herbs For Health, Indian Herbs, and Nature's Fresh Herbs and which contained the following plants or herbs among their ingredients: horsetail, peach kernel, prickly thistle, common nettle, Oregon grape (whole plant or root), devil's club (prickly plant), elderberry (whole plant or root), stinging nettle, wild mountain grape root, Indian berry root, and umbelliferous root; that the articles were accompanied by various items of labeling when the defendants caused the articles to be introduced into interstate commerce, and while the defendants held the articles for sale after shipment in interstate commerce; and that the articles were misbranded as follows:

502(a)—the accompanying labeling of the articles contained false and misleading representations and suggestions that the articles were effective in the cure, mitigation, treatment, and prevention of arthritis, baldness, blood ailments and diseases, cancer, colds, colon troubles and diseases, corns, dandruff, diabetes, diarrhea, dysentery, falling hair, fever, gallbladder troubles and diseases, hemorrhages, hemorrhoids, kidney ailments and diseases, liver troubles and diseases, lung troubles and diseases, menstrual disorders, neuralgia, pain, rheumatism, scalp disorders and ailments, skin diseases and ailments, stomach troubles and diseases, ulcers, urinary ailments and disorders, warts, worms, wounds, and that the articles were effective to guarantee restoration and maintenance of health to the user regardless of the ailment from which he suffered; and

502(f) (1)—the labeling of the articles failed to bear adequate directions for use in all of the disease conditions for which they were intended.

The complaint alleged further that the defendants were causing the abovementioned labeling to accompany the articles while the articles were held for sale after shipment in interstate commerce, which act resulted in the articles being misbranded in the respects set forth above.

Disposition: 10-11-56. The defendants having consented, the court entered a decree of permanent injunction enjoining the defendants and their officers, agents, servants, employees, and all other persons in active concert or participation with any of them, from directly or indirectly doing the following acts with respect to the herbal drugs designated in the complaint, any other drug whose ingredients include any variety of the ingredients described in the complaint, and any other drug intended for the purposes mentioned in the complaint:

(a) introducing into interstate commerce any such drug which is (1) offered for the cure, mitigation, or treatment of arthritis, baldness, blood ailments

<sup>\*</sup> See also No. 5902.

and diseases, cancer, colds, colon troubles and diseases, corns, dandruff, diabetes, diarrhea, dysentery, falling hair, fever, gallbladder troubles and diseases, hemorrhoids, kidney ailments and diseases, liver troubles and diseases, lung troubles and diseases, menstrual disorders, neuralgia, pain, rheumatism, scalp disorders and ailments, skin diseases and ailments, stomach troubles and diseases, ulcers, urinary ailments and disorders, warts, worms, wounds; or (2) which is offered to restore, maintain, or improve the health of the user; or

(b) doing any act with respect to such drug while such drug is held for sale after shipment in interstate commerce, which results in said drug being offered for any of the conditions or purposes described in paragraph (a) above.

## 5904. Keystone Blood and Kidney Remedy. (Inj. No. 303.)

Petition Filed: 12-10-56, W. Dist. Wash., against Otto Soles, Portland, Oreg., to show cause why he should not be punished for criminal contempt for violation of the permanent injunction which had been entered against him on 10-11-56 (see preceding notice of judgment No. 5903).

CHARGE: The petition alleged that the defendant, in violation of the injunction, on 11-28-56, caused to be delivered for introduction into interstate commerce, at Portland, Oreg., consigned to Terre Haute, Ind., and Dayton, Ohio, a number of bottles of a drug designated as Keystone Blood and Kidney Remedy and containing herbs and organic minerals; that the drug was accompanied by leaflets entitled "Keystone Laboratories – The Drug Trust has subsidized" and "Keystone Laboratories – Keystone Blood and Kidney Remedy"; and that the labeling of the drugs, consisting of the bottle labels and accompanying leaflets, offered the drug for the cure, mitigation, treatment, and prevention of blood ailments and diseases, cancer, lung troubles and diseases, menstrual disorders, pain, ulcers, urinary ailments and disorders, and worms, and to restore, maintain, and improve the health of the user; and that by reason of such deliveries the defendant was in criminal contempt of the injunction.

DISPOSITION: On 12-10-56, the order to show cause was issued. On 12-17-56, the defendant having stipulated to a judgment of contempt, the court imposed a 6 months jail sentence which was suspended and placed the defendant on probation for 3 years.

**5905.** Dermaden. (F.D.C. No. 42782. S. No. 42–410 P.)

QUANTITY: 2 display ctns., each containing 8 120-cc. btls., and 16 240-cc. btls., at Seattle, Wash.

Shipped: 9-22-58, from Portland, Oreg., by Consumer Drug Corp.

Label in Part: (Btl.) "Dermaden \* \* \* A Penicillin-Like Skin Application \* \* \* Antibiotic-Anaesthetic-Fungicidal. Distributed by Consumer Drug Corporation, Portland, Oregon \* \* \* Contains .01% Diatrex (Disodium-ethylene-diamine-tetracetate), 1% Benzocaine, 1% Salicylic Acid, 1% Resorcin, 2% Methyl Salicylate, 0.5% Phenol, 0.02% Tyrothricin in special greaseless, non-staining, Ultra-Microscopic Base"; (display ctn.) "Dermaden—Fights Fiery Itching, Promotes Healing, Combats Infection \* \* \* Contains U-M-B A New Concept in "Sustained Action" Skin Medication \* \* \* in addition to its antiseptic content, the very base of Dermaden is anti-bacterial and absorbs toxins \* \* \* Product of Consumer Drug Corporation."

Libeled: About 1-15-59, W. Dist. Wash.